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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,804	07/23/2003	Subhashis Banerjee	BBC-156	9032

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,804	BANERJEE, SUBHASHIS	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to a method for detecting a deantigenized T cell epitope having a binding affinity to a soluble MHC class I molecule and a method for generating a modified polypeptide, classified in Class 435, subclass 7.1.

II. Claims 1-7, drawn to a method for detecting a deantigenized T cell epitope having a binding affinity to a soluble MHC class II molecule and a method for generating a modified polypeptide, classified in Class 435, subclass 7.1.

III-VIII. Claims 8 and 12-16, drawn to a deantigenized MHC class I T cell epitope and a modified polypeptide comprising the said epitope, and pharmaceutical composition thereof, classified in Class 530, subclass 328 and Class 424, subclass 185, respectively.

a. III is a deantigenized MHC class I T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is an antibody.

b. IV is a deantigenized MHC class I T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is an enzyme.

c. V is a deantigenized MHC class I T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is an adjuvant, vector and host cell thereof.

d. VI is a deantigenized MHC class I T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is a carrier.

e. VII is a deantigenized MHC class I T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is a receptor.

f. VIII is a deantigenized MHC class I T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is a ligand, vector and host cell thereof.

Note Absent evidence to the contrary, each of the recited modified polypeptides comprising a deantigenized MHC class I T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

IX-XIV. Claims 8 and 12-16, drawn to a deantigenized MHC class II T cell epitope and a modified polypeptide comprising the said epitope, and pharmaceutical composition thereof, classified in Class 530, subclass 327 and Class 424, subclass 185.1, respectively.

a. IX is a deantigenized MHC class II T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is an antibody.

b. X is a deantigenized MHC class II T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is an enzyme.

c. XI is a deantigenized MHC class II T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is an adjuvant, vector and host cell thereof.

d. XII is a deantigenized MHC class II T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is a carrier.

e. XIII is a deantigenized MHC class II T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is a receptor.

f. XIV is a deantigenized MHC class II T cell epitope and a modified polypeptide comprising a deantigenized T cell epitope, said polypeptide is a ligand.

Note Absent evidence to the contrary, each of the recited modified polypeptides comprising a deantigenized MHC class II T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

XV-XX. Claims 9-11 and 18-20, drawn to a polynucleotide encoding a deantigenized MHC class I T cell epitope and a polynucleotide encoding a modified polypeptide that comprises the said epitope, expression vector and host cell thereof, classified in Class 536, subclass 23.5 and Class 435, subclasses 320.1 and 252.3, respectively.

a. XV is a polynucleotide encoding a deantigenized MHC class I T cell epitope and wherein a polynucleotide encoding a modified polypeptide comprising a deantigenized T cell epitope is an antibody, and vector and host cell thereof.

b. XVI is a polynucleotide encoding a deantigenized MHC class I T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is an enzyme, and vector and host cell thereof.

c. XVII is a polynucleotide encoding a deantigenized MHC class I T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is an adjuvant, and vector and host cell thereof.

d. XVIII is a polynucleotide encoding a deantigenized MHC class I T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is a carrier, and vector and host cell thereof.

e. XIX is a polynucleotide encoding a deantigenized MHC class I T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is a receptor, and vector and host cell thereof.

f. XX is a polynucleotide encoding a deantigenized MHC class I T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is a ligand, and vector and host cell thereof.

Note Absent evidence to the contrary, each of the recited modified polynucleotides polypeptides encoding polypeptides comprising a deantigenized MHC class I T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

XXI-XXVI. Claims 9-11 and 18-20, drawn to a polynucleotide encoding a deantigenized MHC class II-restricted T cell epitope and a polynucleotide encoding a modified polypeptide that comprises the said epitope, expression vector and host cell thereof, classified in Class 536, subclass 23.5 and Class 435, subclasses 320.1 and 252.3, respectively.

a. XXI is a polynucleotide encoding a deantigenized MHC class II T cell epitope and wherein a polynucleotide encoding a modified polypeptide comprising a deantigenized T cell epitope is an antibody, and vector and host cell thereof.

b. XXII is a polynucleotide encoding a deantigenized MHC class II T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is an enzyme, and vector and host cell thereof.

c. XXIII is a polynucleotide encoding a deantigenized MHC class II T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is an adjuvant, and vector and host cell thereof.

d. XXIV is a polynucleotide encoding a deantigenized MHC class II T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is a carrier, and vector and host cell thereof.

e. XXV is a polynucleotide encoding a deantigenized MHC class II T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is a receptor, and vector and host cell thereof.

f. XXVI is a polynucleotide encoding a deantigenized MHC class II T cell epitope and wherein a modified polypeptide comprising a deantigenized T cell epitope is a ligand, and vector and host cell thereof.

Note Absent evidence to the contrary, each of the recited modified polynucleotides polypeptides encoding polypeptides comprising a deantigenized MHC class I T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

XXVII-XLII. Claim 17, drawn to a method of preventing or treating a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class I T cell epitope, classified in Class 424, subclass 130.1.

a. XXVII is method using a modified polypeptide comprising a deantigenized T cell epitope that is an antibody.

b. XXVIII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an enzyme.

c. XXIX is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an adjuvant.

d. XL is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a carrier.

e. XLI is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a receptor.

f. XLII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a ligand.

Note Absent evidence to the contrary, each of the recited polypeptides comprising a deantigenized MHC class I T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

XLIII-XLVIII. Claim 17, drawn to a method of preventing or treating a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class II T cell epitope, classified in Class 424, subclass 185.1.

a. XLIII is method using a modified polypeptide comprising a deantigenized T cell epitope that is an antibody.

b. XLIV is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an enzyme.

c. XLV is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an adjuvant.

d. XLVI is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a carrier.

e. XLVII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a receptor.

f. XLVIII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a ligand.

Note Absent evidence to the contrary, each of the recited polypeptides comprising a deantigenized MHC class I T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

XLIX-LXIV. Claim 17, drawn to a method of diagnosing a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class I T cell epitope, classified in Class 435, subclass 7.1.

a. XLIX is method using a modified polypeptide comprising a deantigenized T cell epitope that is an antibody.

b. LX is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an enzyme.

c. LXI is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an adjuvant.

d. LXII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a carrier.

e. LXIII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a receptor.

f. LXIV is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a ligand.

Note Absent evidence to the contrary, each of the recited polypeptides comprising a deantigenized MHC class I T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

LXVI-LXX. Claim 17, drawn to a method of diagnosing a disease or disorder in a vertebrate, comprising using a modified polypeptide comprising a deantigenized MHC class II T cell epitope, classified in Class 435, subclass 7.1.

a. LXVI is method using a modified polypeptide comprising a deantigenized T cell epitope that is an antibody.

b. LXVII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an enzyme.

c. LXVIII is a method using a modified polypeptide comprising a deantigenized T cell epitope that is an adjuvant.

d. LXIX is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a carrier.

e. XLIX is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a receptor.

f. LXX is a method using a modified polypeptide comprising a deantigenized T cell epitope that is a ligand.

Note Absent evidence to the contrary, each of the recited polypeptides comprising a deantigenized MHC class I T cell epitope is distinct since each ligands(s) to which each of said polypeptides bind is specific for is not obvious over the other set of ligand(s). Therefore the instant claims encompass hundreds of GROUPS, not species.

2. Inventions listed as Groups (III-VIII) and Groups (XXVII-XLII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

3. Inventions listed as Groups (IX-XIV) and Groups (XLIII-XLVII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

4. Inventions listed as Groups (III-VIII) and Groups (XLIX-LXIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an immunogen.

5. Inventions listed as Groups (IX-XIV) and Groups (LXVI-LXX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as an immunogen.

6. The Inventions listed as Group I, Group II, Groups (XXVIII-XLVIII), Groups (XLIII-XLVIII), Groups (XLIX-IXIV) and Groups (LXVI-LXX) are different methods.

These inventions require different ingredients, process steps and endpoints to accomplish the use of: detecting a deantigenized T cell epitope and generating a modified polypeptide comprising the said epitope (Inventions listed as Groups I and II), of preventing or treating a disease or disorder in a vertebrate comprising administering a modified polypeptide comprising a deantigenized T cell epitope (Inventions listed as

Groups XXVII-XLII and XLIII-XLVIII), diagnosing a disease or disorder in a vertebrate using a polypeptide comprising a deantigenized T cell epitope (Inventions listed as Groups XLIX-LXIV and LXVI-LXX). In addition, the method of detecting a deantigenized T cell epitope and generating a polypeptide, the method of preventing or treating a disease or disorder and the method of diagnosing a disease or disorder either detect or use one of either an MHC class I deantigenized epitope or polypeptide comprising said epitope (Inventions listed as Groups, I, XXVII-XLII, XLIX-LXIV) or an MHC class II deantigenized epitope or polypeptide comprising said epitope (Inventions listed as Groups II, XLIII-XLVIII, LXVI-LXX). MHC class I epitopes are bound by MHC class I molecules and elicit T cells restricted by MHC class II, whereas MHC class II epitopes are bound by MHC class II molecules and elicit T cells restricted by MHC class II.

7. Inventions listed as Groups (III-VIII), Groups (IX-XIV), (XV-XX) and Groups (XXI-XXVI) are different products.

Proteins and polypeptides ((III-VIII) and (IX-XIV)) are distinct from polynucleotides ((XV-XX) and (XXI-XXVI)) because their structures and modes of action are different. Proteins are comprised of amino acid residues and polynucleotides are comprised of nucleotides. In addition, deantigenized class I MHC T cell epitopes are distinct from deantigenized class II MHC T cell epitopes because they have different physicochemical structures and have reduced or absent binding to class I or class II MHC, respectively, and affect differently restricted T cell responses.

8. Inventions listed as Group I and Groups (III-VIII) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)).

In the instant case, a known T cell epitope may be subjected to an Alanine scan of each position in the peptide, and the altered epitope possessing low to absent binding may be substituted into the native protein sequence in place of the T cell epitope.

9. Inventions listed as Group II and Groups (IX-XIV) are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)).

In the instant case, a known T cell epitope may be subjected to an Alanine scan of each position in the peptide, and the altered epitope possessing low to absent binding may be substituted into the native protein sequence in place of the T cell epitope.

Therefore they are patentably distinct.

10. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-LXX is not required for any other group from Groups I-LXX and Groups I-LXX have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

11. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. **Irrespective of whichever group Applicant may elect**, Applicant is further required to (1) elect a single disclosed species of dissociation constant for the binding of the deantigenized T cell epitope to MHC (for example, greater than or equal to about 5 x 10^{-5} M) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they bind to MHC with different affinities.

13. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

14. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

15. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

17. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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